IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

MEDFORD DIVISION

JOHN GILLMAN; and BEN DEVRIES,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION; and DOE 1,

Defendants.

Civil No. 11-3067-CL

REPORT AND RECOMMENDATION

CLARKE, Magistrate Judge:

Plaintiffs filed an amended complaint alleging claims arising out of the surgical implant of a spinal cord stimulator. Plaintiffs seek economic damages and noneconomic damages, and costs and reasonable attorney fees. This court has jurisdiction pursuant to 28 U.S.C. § 1332. Defendant Boston Scientific Corporation has filed a motion to dismiss plaintiffs' amended complaint (#13) pursuant to Federal Rules of Civil Procedure 12(b)(6). The time for a response has passed and no response to the motion has been filed.[1] For the reasons explained below,

[1] After the amended complaint was filed, the court granted plaintiffs' counsel's motion to withdraw as attorney. The certificates of service attached to defendant's motion to dismiss show that plaintiffs, who are proceeding pro se, were served at their address of record.

defendant's motion to dismiss should be granted.

LEGAL STANDARDS

In considering whether a complaint states a claim for relief under Rule 12(b)(6), the factual allegations, taken as true, must be sufficient "to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A plaintiff must plead sufficient facts to "'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009) (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556); Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir. 2009). Further, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Twombly, 550 U.S. at 555.

In considering a motion to dismiss, the court accepts the complaint allegations of material fact as true and construes these allegations in favor of the non-moving party. N. County Cmty. Alliance, Inc. v. Salazar, 573 F.3d 738, 741-42 (9th Cir. 2009), cert. denied, ___ U.S. ___, 130 S. Ct. 2095 (2010).

BACKGROUND

In their amended complaint, plaintiffs allege defendant Boston Scientific "designed, researched, manufactured, tested, marketed, advertised, promoted, distributed, and sold Advanced Bionics spinal cord stimulator and battery" (stimulator), a device surgically placed

under a patient's skin to send mild electric current to the spinal cord to relieve chronic pain. "The Food and Drug Administration approved [the] stimulator on September 30, 2004 for treatment of pain." (Am. Compl. ¶ 15.) Subsequent to this approval, defendant continued to advertise and market the stimulator as a safe and effective method of controlling pain.

Plaintiff Gillman was implanted with a stimulator on or about April 2009. Such "stimulator failed, malfunctioned, was/became defective and/or failed to work properly." (Am. Compl. ¶ 8.) Plaintiff had the device surgically removed. Plaintiff's spine "will never be whole again and he will never fully recover from the surgical removal of [the] stimulator." (Am. Compl. ¶ 11.)

Plaintiff alleges claims against defendant for 1) products liability; 2) negligence; 3) loss of consortium; 4) breach of implied warranty; 5) breach of express warranty; 6) negligent misrepresentation; and 7) failure to warn.

DISCUSSION

Federal Preemption Under Medical Device Amendments and Riegel v. Medtronic, Inc.

Defendant first contends that plaintiffs' claims related to the stimulator are preempted by the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360c et seq., to the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. The MDA includes an express preemption provision that provides, with an exception not applicable here, that,

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. For a state law cause of action to be preempted, there must be "(1) a federal requirement imposed on the device under the FDCA, and (2) the challenged state or local rule must impose a requirement that is different from, or adds additional obligations to, the federal requirement." Degelmann v. Advanced Med. Optics Inc., 659 F.3d 835, 841 (9th Cir. 2011) (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 321-22 (2008)).

In their amended complaint, plaintiffs specifically allege "The Food and Drug Administration approved [the] stimulator on September 30, 2004 for treatment of pain." (Am. Compl. ¶ 15); see 69 Fed. Reg. 58, 446-01 (Sept. 30, 2004) (notice that PMA No. P030017/ 2004M-1256 by Advanced Bionics Corp. for Precision Spinal Cord Stimulation (SCS) System was approved April 27, 2004); http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030017A.pdf (PMA approval letter).[2] Premarket approval (PMA) is the most rigorous review and is imposed on Class III devices.[3] The Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312, 322-23

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[2] The court may take judicial notice of the contents of the Federal Register and FDA documents, which are matters of public record, without converting defendant's motion to dismiss into one for summary judgment. See 44 U.S.C. § 1507; 21 C.F.R. § 814.44(d); Funk v. Stryker Corp., 673 F. Supp.2d 522, 530 (S.D. Tex. 2009) ("[T]he [PMA] process is a matter of public record . . . and 'it is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.'" (Quoting Norris v. Hearst Trust, 500 F.3d 454, 461 n.9 (5th Cir. 2007)), aff'd, 631 F.3d 777 (5th Cir. 2011); Lee v. City of L.A., 250 F.3d 668, 688-89 (9th Cir. 2001) ("[U]nder Fed.R.Evid. 201, a court may take judicial notice of 'matters of public record.'"), impliedly overruled on another ground as discussed in Gallardo v. DiCarlo. 203 F. Supp.2d 1160 (C.D. Cal. 2002).

[3] Class III devices are devices "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or [] presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

The district court in Horn v. Boston Scientific Neuromodulation Corp., No. CV409-074, 2011 WL 3893812, at *3 (S.D. Ga. Aug. 26, 2011), stated that the "Precision Spinal Cord Stimulator" was a Class III device subject to the PMA process.

(2008), determined that premarket approval "imposes 'requirements' under the MDA." PMA is specific to individual devices and "*is* federal safety review." Id. PMA is given only if the FDA determines the approved form of a device "provides a reasonable assurance of safety and effectiveness." Id. (citing 21 U.S.C. § 360e(d)). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(I)).

Following the Riegel decision, courts have applied section 360k(a) preemption provision broadly to preempt state claims such as strict products liability, negligence, negligence per se, manufacturing and design defect, breach of warranty, and failure to warn. See *In re* Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp.2d 1147, 1152 (D. Minn. 2009), aff'd, 623 F.3d 1200 (8th Cir. 2010).

Thus, whether plaintiffs' claims are preempted in this case will be determined at the second step -- whether plaintiffs' claims would impose a requirement different from or additional to requirements imposed by the FDCA/MDA. In this regard, the Riegel Court determined that reference to a state's "requirements" includes its common-law legal duties. 552 U.S. at 324-25 ("State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect.") (and cases cited interpreting other preemption provisions in accord).

Plaintiffs' Claims for Products Liability and Negligence

Plaintiff Gillman's claim for products liability is premised on the allegation that the risk outweighed any benefit and the stimulator did not perform in a safe manner. His negligence

claim is premised on an alleged failure to exercise ordinary care in the research, development, design, manufacture, testing, marketing, advertising, promotion, sale and distribution of the stimulator. For plaintiff to prevail on these claims would clearly impose requirements different from or additional to those imposed by the FDCA/MDA. See Riegel, 552 U.S. at 323-25; Horn v. Boston Scientific Neuromodulation Corp., No. CV409-074, 2011 WL 3893812, at *4-*6 (S.D. Ga. Aug. 26, 2011) (design, manufacture, preparation, testing, instruction and warnings). Plaintiffs' claims for products liability and negligence is preempted and defendant's motion to dismiss these claims should be granted.

Plaintiffs' Claims for Breach of Implied Warranty, Breach of Express Warranty, and Negligent Misrepresentation

The breach of implied warranty alleges warranties relating to the stimulator's merchantability, safety, and fitness for use, and relief from chronic pain. The breach of express warranty claim alleges defendant warranted in publications and other communications for medical patients and the public that the stimulator was safe, effective, fit and proper for intended use. Plaintiff's negligent misrepresentation claim is premised on allegations that defendant misrepresented the safety and efficacy of the stimulator for use in relieving chronic pain. These claims, as alleged, would impose different or additional requirements. Notably, the PMA approval letter for the stimulator states "This device is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs . . . ." http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030017A.pdf; see Parker v. Stryker Corp., 584 F. Supp.2d 1298, 1300, 1303 (D. Colo. 2008) (finding claims for breach of implied warranties of

fitness and merchantability preempted); Miller v. DePuy Spine, Inc., 638 F. Supp.2d 1226, 1230 (D. Nev. 2009) ("Where, as here, an essential element of a plaintiff's claim for breach of express or implied warranty will be proof that a device granted a PMA is not safe or effective, such a contention necessarily conflicts with the FDA's contrary finding and its requirement that the device be made as approved.").

Although plaintiffs' sixth claim for negligent representation focus on injury due to the safety and efficacy of the stimulator, in the factual allegations, plaintiffs allege with regard to their allegation that defendant misrepresented the stimulator as being "'easy in, easy out,'": "Defendants further represented that there were physicians readily available in all fifty states who were knowledgeable with [the] stimulator and could easily maintain, service, and remove [the] stimulator, if necessary or requested"; plaintiff Gillman advised defendant he would be moving to Oregon and "Defendants specifically stated that they had physicians ready, available, knowledgeable, and willing to maintain, service, and remove such stimulator." (Am. Compl. ¶¶ 10, 11.) While these allegations could be construed as going to the efficacy of the stimulator, construing the allegations in plaintiffs' favor, the court concludes they go beyond allegations relating to the safety and effectiveness of the stimulator or other matter included in a requirement applicable to the device so as to be preempted. This part of plaintiffs' claim for negligent misrepresentation is not preempted.[4]

However, to state a claim for negligent misrepresentation under Oregon law, plaintiff Gillman must allege facts of a "special relationship" between himself and defendant Boston

[4] Defendant addresses these allegations as a breach of express warranty claim, but since the alleged representations do not relate to the device, the court construes the allegations as a negligent misrepresentation claim.

Scientific which imposes a heightened standard of care. A special relationship exists where one party in a relationship owes a duty "'beyond the common law duty to exercise reasonable care to prevent foreseeable harm' to the other party," that is, the nature of the relationship is such that, "one party has authorized the other to exercise independent judgment in his or her behalf and, consequently, the party who owes the duty has a special responsibility to administer, oversee, or otherwise take care of certain affairs belonging to the other party." Conway v. Pac. Univ., 324 Or. 231, 236 (1996). Examples of special relationships include attorney-client, patient-physician, principal-agent, and trustee-beneficiary relationships. Id. at 240.

Here, plaintiffs allege only an ordinary duty or standard of care. They do not allege any facts of a special relationship between plaintiff Gillman and defendant, nor does it appear they could do so.

To the extent that plaintiffs' claim for negligent misrepresentation is not preempted, it fails to state a claim for relief. Defendant's motion to dismiss plaintiffs' breach of warranty claims and negligent misrepresentation claims should be granted.

Plaintiffs' Claim for Failure to Warn

Plaintiff Gillman alleges in his failure to warn claim that defendant failed to provide warning of known risks and dangers of the stimulator to him and his medical providers. He specifically alleges in the factual allegations defendant failed to warn that implantation and removal of the stimulator "was not a simple procedure and that there are many adverse side effects associated with [the] stimulator, especially a defective and/or malfunctioning stimulator." (Am. Compl. ¶ 16.) These allegations relate to the safety and effectiveness of the stimulator and

plaintiff clearly seeks to impose by reason of state law different or additional warnings than the labeling, information and warnings for the device included in the PMA process. See *In re* Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205 (8th Cir. 2010); Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011). Plaintiffs' failure to warn claim is preempted and defendant's motion to dismiss this claim should be granted.

Possibility of a "Parallel" Claim under Riegel

The Riegel Court left open the possibility of a damages remedy premised on a violation of FDA regulations, described as a "'parallel'" claim. Riegel, 552 U.S. at 330; see Parker, 584 F. Supp.2d at 1300-02; but see *In re* Medtronic, 592 F. Supp.2d at 1160-62 (implied preemption). The court has reviewed plaintiffs' amended complaint and, construing the allegations in their favor, finds plaintiffs do not allege defendant violated any federal MDA regulation so as to allege any such parallel claim.

Defendant's motion on this ground should be granted.

Plaintiffs' Claim for Loss of Consortium

In their third cause of action following claims for products liability and negligence, plaintiffs allege a claim for loss of consortium as a result of the alleged wrongful and negligent acts of defendant. A claim for loss of consortium is considered to be a derivative claim and dependent upon resolution of plaintiff Gillman's claims. Because the court has found plaintiff Gillman's claims preempted or otherwise insufficient, Plaintiff Devries' claim for loss of consortium should be dismissed. Knepper v. Brown, 213 Or. App. 598, 609 (2007), aff'd, 345

Or. 320 (2008); McCloskey v. United Parcel Serv. Gen. Servs. Co., No. Civ. 95-420-FR, 1998 WL 126865, at *14 (D. Or. Mar. 17, 1998); Walleri v. Fed. Home Loan Bank of Seattle, Civ. Nos. 90-0855-AS, 91-1222-AS, 1993 WL 566023 (D. Or. Nov. 9, 1993). Defendant's motion to dismiss in this regard should be granted.

Conclusion

Plaintiff Gillman's claims for products liability, negligence, breach of implied warranty, breach of express warranty, and failure to warn are preempted by the MDA and FDCA and should be dismissed. Plaintiff Gillman's claim for negligent representation is preempted in part; to the extent the claim is not preempted, it fails to state a claim for relief and should be dismissed. Plaintiff Devries' derivative claim for loss of consortium should be dismissed. Because it does not appear that plaintiffs could amend their complaint to state any claim for relief on the facts alleged, and plaintiffs have not responded to defendant's motion and proposed amending their complaint, this case should be dismissed without leave to amend.

RECOMMENDATION

Based on the foregoing, it is recommended that defendant's motion to dismiss (#13) be granted and this case dismissed without leave to amend, and that judgment be entered accordingly.

This recommendation is not an order that is immediately appealable to the Ninth Circuit Court of Appeals. Any notice of appeal pursuant to Rule 4(a)(1), Federal Rules of Appellate Procedure, should not be filed until entry of the district court's judgment or appealable order.

The Report and Recommendation will be referred to a district judge. *Objections to this Report and Recommendation, if any, are due by February 14, 2012. If objections are filed, any response to the objections are due by March 2, 2012, see Federal Rules of Civil Procedure 72 and 6.*

Failure to timely file objections to any factual determinations of the Magistrate Judge will be considered a waiver of a party's right to de novo consideration of the factual issues and will constitute a waiver of a party's right to appellate review of the findings of fact in an order or judgment entered pursuant to the Magistrate Judge's recommendation.

DATED this 27 day of January 2012.

MARK D. CLARKE
UNITED STATES MAGISTRATE JUDGE